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SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant

Nihon Kohden America, Inc.

90 Icon St.
Foothill Ranch, Ca 92610

Phone: (949) 580-1555
Dial 9 and then Ext. 4401
Fax: (949) 580-1550
Attn: Serrah Namini,
Regulatory Affairs Assoc. Dir.

Indications for Use:

The device, ZS-940PA series, is intended to transmit physiological data, such as: electrocardiogram (ECG), respiration, blood oxygen saturation (SpO_2), noninvasive blood pressure (NIBP), and pulse waveform from a patient to a Nihon Kohden monitor for continuous monitoring applications. The transmitter can change channels when connected to the QI-910PK channel writer. The front LCD displays SpO_2%, NIBP, pulse rate, pulse waveform amplitude, electrode condition mark, battery condition and NIBP measuring mode and interval. The system communicates in the new WMTS band as required by FCC. The monitored physiological parameters communicated via radiofrequency can be displayed, stored and printed at a Nihon Kohden Central monitor, such as WEP-4000 or ORG-9700/CNS-9700.

The device will be available for sale only upon the order of a physician or licensed health care provider and it will be available for use by medical personnel on all patient populations within a medical facility, including ICU, CCU, recovery room and general ward.

The device complies with IEC 60601-1 sub-clause 56.3(c) implemented by 21 CFR Part 898 Performance Standard for Electrode Lead Wires and Patient Cables. The device is also in compliance with applicable sections of IEC standard as listed in this application.

Sterilization is not required for the device.

The device does not directly contact patients; It is place in a pocket of a non-latex blood pressure cuff on a patient's arm. Accessories that contact patients, such as SpO_2 probes, are the same accessories as used with other legally marketed products or are comprised of the same component materials as the accessories of predicate devices. Therefore, good laboratory practice studies required per 21 CFR Part 58 are not applicable for this submission.

The device was subject to electromagnetic, environmental, safety and performance testing procedures. These tests verified the intended operation of the device. Safety and efficacy was documented through Design validation of the software and hardware of the device.

Therefore, Nihon Kohden believes that the device is substantially equivalent to the Nihon Kohden predicate devices.

SECTION 3 - PROPOSED LABELING

A. Intended Use

The device is intended to monitor, display and transfer physiological data. Specifically, the device is intended to monitor heart rate, pulse rate, blood oxygen saturation (SpO_2), respiratory rate, and non- invasive blood pressure (NIBP). This device may be used to transmit physiological signals via radio frequency. The device will be available for use by medical personnel on all patient populations within a medical facility.

B. Device/Package Labels

The proposed product labels for the device are located in Attachment # A .

C. Proposed Packaging

Packaging drawings/ specifications for the device is depicted in Attachment # A.

D. Instructions for Use

The proposed instructions for use is provided with each packaged device and is presented in Attachment # H, Operator's Manual .

E. Advertisement/Promotional Literature

To date, no advertisement or promotional literature has been created for the distribution in the United States.

F. Contraindications, Precautions & Warnings

Warnings and Cautions listed in the Operator's Manual are depicted in Attachment # B.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Nihon Kohden America, Inc.
c/o Ms. Serrah Namini
RA Associate Director
90 Icon St.
Foothill Ranch, CA 92610

Re: K043517
Trade Name: ZS-940PA Transmitter
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: DRT
Dated: December 16, 2004
Received: December 20, 2004

Dear Ms. Namini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zimmerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

G. Indications for Use Statement

510(k) Number (if known): K043517

Device Name: ZS-940PA Series

Indications for Use:

The device is intended to transmit physiological data, such as: electrocardiogram (ECG), respiration, blood oxygen saturation (SpO_2), noninvasive blood pressure (NIBP), and pulse waveform from a patient to a Nihon Kohden monitor for continuous monitoring. The transmitter can change channels when connected to the QI-910PK channel writer. The front LCD displays SpO_2%, NIBP, pulse rate, pulse waveform amplitude, electrode condition mark, battery condition and NIBP measuring mode and interval. The system communicates in the new WMTS band as required by FCC. The device will be available for use within a medical facility, including ICU, CCU, recovery room and general ward by medical personnel on adults and children for NIBP and all other functions for all patient populations, including neonates.

Prescription Use __X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K043517 B Cummings

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number_____